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February 25, 2020

VIA ECF

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey
Mitchell H. Cohen Building & U.S.
Courthouse
4th & Cooper Streets, Courtroom 3C
Camden, NJ 08101

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Schneider:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the Case Management Conference with the Court on February 26.

1. Downstream Defendant Discovery

(a) Retailer Macro Discovery Issues

During the February 13 discovery conference, the Court directed the Retail Pharmacy Defendants and Plaintiffs to continue to meet and confer regarding the scope of proposed discovery, and to exchange and identify for the Court a proposed list of "macro" discovery issues for briefing. Since the February 13 conference, the parties have had several productive conversations regarding the scope of proposed Rule 34 document requests and proposed Defendant Fact Sheet (DFS). The Retail Pharmacy Defendants received Plaintiffs' latest redline of the Rule 34 requests on Monday, February 24. As of the time of this filing, Plaintiffs were working on revisions to the Retail Pharmacy Defendants' proposed DFS, and advised that a redline was forthcoming. Counsel for the Retail Pharmacy Defendants are reviewing the latest drafts and will

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confer with each other and with their clients, but based on the ongoing conversations with Plaintiffs, hope that additional negotiations will continue to narrow the issues that require Court intervention, understanding that there may ultimately be certain topics that require briefing and Court intervention. Accordingly, as the parties continue to work together to narrow the scope of issues to raise with the Court, the Retail Pharmacy Defendants identify the following preliminary list of macro discovery issues, which may require briefing (and which these defendants reserve the right to brief), along with a preview of the issues in dispute:

- **Definition of “valsartan” and “relevant time period” as they relate to scope of production:** Throughout their proposed discovery, Plaintiffs have requested documents related to all valsartan purchased from the named manufacturers in the litigation and sold to any consumer since generic valsartan was approved for sale in 2012, without limitation to the relevant recall period, to the named plaintiffs in the litigation, or to the claims set forth in the various master complaints. Given the number of manufacturers named in the MDL, this essentially amounts to a request that the Retail Pharmacy Defendants produce extensive documents reflecting the majority of their sales data and customer rolls for nearly a decade. The Retail Pharmacy Defendants object generally to these broad definitions on the grounds of relevance, proportionality, burden, and commercial sensitivity.
- **Scope of production of dispensing records for non-plaintiff consumers:** Similarly, Plaintiffs have requested dispensing records for every sale of valsartan from 2012 to present, without limitation to the relevant recall period, to the named plaintiffs in the litigation, or to the claims set forth in the various master complaints. The Retail Pharmacy Defendants have offered to produce dispensing records for named personal injury plaintiffs and class representatives, and object to production of consumer dispensing records beyond those of named plaintiffs on the grounds of relevance, proportionality, privacy, and burden.
- **Pricing information concerning Retailer Pharmacy Defendants’ purchase of valsartan:** Plaintiffs have requested that the Retail Pharmacy Defendants produce information on the gross and net price for each valsartan purchase made by the Retail Pharmacy Defendants, and have advised that such information is demanded at “as granular a level as possible.” The Retail Pharmacy Defendants object to this request on grounds of relevance, given the claims asserted by Plaintiffs and Plaintiffs’ pleaded model of damages, and on grounds of burden and commercial sensitivity.
- **Information concerning downstream prices paid by all consumers and all TPPs for valsartan:** Plaintiffs also have requested that the Retail Pharmacy Defendants produce information on the “gross and net price” paid by all consumers and all TPPs for all valsartan dispensed since 2012, regardless of whether the consumer is a plaintiff in this litigation. As the Retail Pharmacy Defendants understand Plaintiffs’ current draft document requests, Plaintiffs also seek this information on “as granular a level as possible.” As with the upstream pricing information, the Retail Pharmacy Defendants object to this request on

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grounds of relevance, given the claims asserted by Plaintiffs and Plaintiffs' pleaded model of damages, and on grounds of burden and commercial sensitivity.

- **Document retention policies:** Plaintiffs have requested that the Retail Pharmacy Defendants produce document retention and destruction policies for all issues "pertinent" to their proposed Requests. The Retail Pharmacy Defendants do not believe that discovery on document retention policies comports with the Court's directions on the scope of discovery to downstream defendants, or that such discovery is necessary for the pre-trial workup of the economic loss action (or any other matter to be selected for pre-trial work-up), and therefore object on relevance grounds and the grounds that such discovery is premature at this stage of the litigation.
- **Indemnification agreements and related documents:** Similarly, Plaintiffs have requested that the Retail Pharmacy Defendants produce all agreements with any party that affect these defendants' "legal obligations or liabilities" in the litigation. The Retail Pharmacy Defendants object to discovery on indemnity agreements and other contractual agreements as unnecessary to the issues in dispute and, if relevant at all, premature at this stage of the litigation.
- **Valsartan returns:** In their proposed DFS, Plaintiffs request that the Retail Pharmacy Defendants perform a search for documents reflecting returned valsartan for any plaintiff completing a PFS. Defendants have proposed to perform a search for return records triggered by the named plaintiff's response to the PFS—i.e., that if the plaintiff reports that he/she may have or did return valsartan to a pharmacy, the respective pharmacies will then search for and provide records. Plaintiffs instead contend that an affirmative search should be performed irrespective of whether there is any evidence that return records exist. The Retail Pharmacy Defendants object to this proposal on the grounds of burden and disproportionality.

Again, the above is meant to briefly preview for the Court issues to be resolved in the parties' continuing meet and confer efforts, and otherwise, to be briefed for the Court at a future date. In the event that additional issues are raised in the course of the parties' negotiations or in light of later revisions to the draft documents, the Retail Pharmacy Defendants reserve the right to raise these issues with Plaintiffs and the Court as additional macro issues for the Court's consideration.

(b) Wholesaler Macro Discovery Issues

1. **Most Important Information:** The dominant issue before the Court, which should act to inform its decisions on the below macro discovery issues ("Macro Issues"),¹ is

¹ Wholesaler Defendants are not appearing in the Economic Loss case in which they not been named as Defendants, but address macro discovery issues pertaining to all three actions – Personal

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Plaintiffs' continued inability to limit their Request for Production ("RFPs") to Wholesalers to a search for only the Most Important Information ("MII"). Of course, MII is necessarily *not everything*, and, as defined by the Court on December 18, 2019, discovery to Wholesalers is meant to "focus on what is genuinely needed and relevant at this stage of the case." Ignoring that instruction, Plaintiffs' proposed RFPs seek to impose a heavy burden² on Wholesalers to produce eight years of expansive and sensitive Company documents, *information that will not, in fact, advance Plaintiffs' liability or damage case*, including:

- the date of each and every purchase of any VCD since January 2012
- the identity of each seller in each and every one of those specific purchases
- the gross and net price for each and every one of those specific purchases
- the date of each and every sale of any VCD since January 2012
- the identity of each buyer in each and every one of those specific purchases
- the gross and net price for each and every one of those specific purchases
- all of the paper packaging and/or labeling information (e.g., invoices, bills of lading, packing slips, etc.) received and/or distributed by Wholesalers with each and every purchase and sale of any VCD since January 2012

These expansive and burdensome discovery requests are even more egregious given the tacit admission by all players in this litigation that there is currently no evidence Wholesalers did anything more than pass pharmaceuticals unchanged from Manufacturer to Retailer, as well as the glaring absence of factual allegations of wrongdoing by Wholesalers in Plaintiffs' Complaints. For these reasons, Wholesalers request the Court again order that Plaintiffs narrow their proposed RFPs to Wholesalers to seek only MII.³

- 2. Absence of facts to support claims of Wholesaler wrongdoing:** It is fundamental that all inquiries into relevance of discovery requests start with an assessment of the allegations made in the complaint. Here, Plaintiffs have failed to assert any factual allegation of wrongdoing against any Wholesaler in any Complaint – not in the

Injury, Medical Monitoring, and Economic Loss – while reserving all 12(b) and other rights, so as to not delay discovery decisions.

² Wholesalers recognize that the Court has noted that there will be an opportunity for full briefing of all of the issues, including the objections of burdensomeness and disproportionality to the needs of the case. Wholesalers will present further detail and full briefing on these issues, including citations to evidence and relevant legal authority, at the appropriate time as indicated by this Court.

³ Of course, as the Court has repeatedly stated, if Plaintiffs need more information as the case proceeds, the Court will permit supplemental requests.

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Personal Injury Master Complaint, not in the Medical Monitoring Class Action Master Complaint, and not in the Economic Loss Class Action Master Complaint (in which Wholesalers have not been named or served).⁴ The absence of allegation of factual wrongdoing is not just on the written page. Counsel for Wholesalers have, on two occasions during meet and confers, directly asked Plaintiffs' counsel to describe the factual allegations of wrongdoing by Wholesalers upon which Plaintiffs base their claims. Plaintiffs' counsel have twice refused to articulate even one such allegation. In light of these failures, the Court should require from Plaintiffs a particular demonstration of relevance to attempt to justify the broad discovery requested; i.e., the burden should rest on Plaintiffs to prove *how* the discovery requested will actually advance their case.

3. **Wholesaler financial information:** Plaintiffs claim Wholesalers should produce eight years of pricing and profit information that is not MII, is highly confidential and proprietary, voluminous, unduly burdensome to produce, and disproportionate to the needs of the case ("Wholesaler Financial Information"). Moreover, the resulting production would not be relevant, and would in fact be immaterial, to: 1) the assessment of the liability of any Defendant; 2) the calculation of Plaintiffs' damages; and 3) the ascertainment of any class (liability or damage).

Plaintiffs' alleged damages are clear: medical expenses and pain and suffering for the Personal Injury Actions, costs to monitor health for the Medical Monitoring Class Action, and amounts expended by Consumers and Third Party Payers ("TPPs") on purchases of VCDs for the Economic Loss Class Action. As a sale of goods case, the appropriate damage model for Plaintiffs' Economic Loss claims consists of the granular data *uniquely possessed only by the Plaintiffs* – the amounts spent by Plaintiffs, plus fees, less discounts, on VCDs.

Yet, Plaintiffs request from Wholesalers the specific amounts paid for each individual purchase of a VCD over the course of eight years, as well as the price charged for each individual sale of a VCD over those eight years. These amounts, specifically (and Wholesalers' profits, more generally), have no bearing whatsoever on the core damages to which Plaintiffs would be entitled. *Wholesaler* Financial Information does not reflect *Plaintiffs'* or even a *class of Plaintiffs'* personal injury, medical monitoring, or economic loss damages.

Wholesalers have specifically requested that Plaintiffs articulate the relevance of this request, and Plaintiffs have replied only that their "expert says he needs it." The Court understands, of course, that this is not the standard for production. Even giving

⁴ Though Plaintiffs have recently provided a draft Amended Economic Loss Class Action Master Complaint which purports to name Wholesalers as Defendants – it, predictably, still makes no factual allegations of wrongdoing as to any Wholesaler.

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Plaintiffs every benefit of the doubt, Wholesaler Financial Information could only *possibly* be relevant to the alleged extraordinary remedy of disgorgement of profits – a remedy for which Plaintiffs have failed to allege any supporting facts. With no allegations of any wrongdoing, much less of fraud, or willful and knowing deception proven by clear and convincing evidence, Plaintiffs’ request is a non-starter. As a result, Wholesalers request that this Court order that Wholesalers need not produce their Financial Information, as it is not MII, is not relevant, is highly confidential and proprietary, would be unduly burdensome to produce, and is disproportionate to the needs of the case.

- 4. Mapping of Wholesaler purchases and sales:** In addition to Plaintiffs’ request that Wholesalers produce Financial Information, Plaintiffs also seek documents reflecting eight-years-worth of the non-financial detail of each and every individual Wholesaler purchase of and sale of VCDs (date, NDC number, lot/batch number, seller, purchaser, price, and volume of individual sale) (“Wholesaler Purchase/Sales Information”). The purported relevance of the request is to assist with Plaintiffs’ product identification obligation, specifically, to try to track the sale of specific lots from an API Manufacturer to a Manufacturer to a Wholesaler to a Retailer down to a specific Consumer. Wholesalers understand Plaintiffs’ desire to try to recreate the pharmaceutical supply chain; the truth is, however, *that no amount of Wholesaler discovery will allow Plaintiffs to map the transfer of product to their individual Plaintiffs’ hands.*

Wholesalers have repeatedly informed Plaintiffs during the meet and confer process that product mapping and identification via the requested documents is impossible. Lot and batch numbers are not passed along the entire supply chain. In most instances, Manufacturers are required to send Wholesalers the lot and batch information. Wholesalers, on the other hand, when they are included in the supply chain,⁵ *are not required to pass on that lot/batch information to Retailers – and do not.* After receipt from the Manufacturers, Wholesalers typically ship product to Retailer distribution centers (without lot/batch number), and those drugs are then shipped from Retailer distribution centers to particular Retailer storefronts. The only lot/batch information that Wholesalers possess is that information originally provided to them by Manufacturers. Wholesalers have no knowledge of which subsequent purchaser receives which lots/batches. *Wholesalers simply do not create, provide, or retain records of where those lot/batches go via their distribution.*

On the other hand, each Plaintiff’s own pharmacy records will identify the Retailer involved and will reflect the NDC number taken, which will identify the Manufacturer. Nothing in Wholesalers’ Sales/Purchase Information could do more than that, or, more

⁵ In many instances, Retailers purchase drugs directly from Manufacturers and Wholesalers will never have touched a given Plaintiff’s drugs.

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specifically, could establish which Wholesaler was involved in transporting a specific pill to a specific Consumer. ***That information is simply not possessed by Wholesalers and could not be re-created with the information available.*** Plaintiffs' specific request for "all of the packaging and/or labeling information (e.g., invoices, bills of lading, packing slips, etc.) received and/or distributed by Wholesalers with each and every purchase and sale of any VCD since January 2012" demonstrates how burdensome Plaintiffs seek to be in this matter. Even if Wholesalers were to go to the incredible time and expense to procure such paper materials for an eight year period, those documents would not further the Plaintiffs' cause. In addition, the limited lot/batch information possessed by Wholesalers – which is in documentation Wholesalers received from Manufacturers – is obviously duplicative of the information the Plaintiffs are already receiving from the Manufacturers; if Wholesalers were made to produce documentation of that information, Plaintiffs would literally be receiving the exact same information twice: once from the Manufacturers who sent it originally, and once from the Wholesalers who received it.

Consequently, Wholesalers ask this Court to order that Wholesalers need not produce Wholesaler Purchase/Sale Information reflecting the detail of each and every purchase and sale of any VCD from or to any entity over an eight year period, as the request is not relevant to the issues in the case, is not MII, does not provide information that would assist in product identification, seeks information that is highly confidential and proprietary, is unduly burdensome, and is disproportionate to the needs of the case.

5. **Recall period versus pre-recall period:** Plaintiffs are well aware that Wholesalers had no knowledge of any problem with the VCDs prior to the recalls in 2018. Wholesalers are agreeable to producing documents relevant to the VCD recall, including policies and procedures governing the execution of the recall, recall communications received by Wholesalers, and recall communications made by Wholesalers. However, Plaintiffs do not limit their requests to the time period of the recall; instead, for each of their requests they seek documents beginning in January 2012. This proposed time period imposes significant, unnecessary burden on Wholesalers to produce documents in various categories which are not relevant, including, in particular, the requests for Wholesaler Financial Information and Wholesaler Purchase/Sales Information as set forth above. Therefore, Wholesalers ask this Court to limit the relevant time period for this set of RFPs to the recall period, which is the time during which Wholesalers were aware there was a potential problem with the VCDs, at least at this stage, pending review of documents from other Defendants.
6. **Recalled v. non-recalled VCDs:** Similarly, Plaintiffs demand expansive records spanning *all VCDs, regardless of whether they were recalled or even manufactured by one of the defendants in this case.* Plaintiffs' "everything but the kitchen sink" approach is contrary to this Court's spirit of discovery regarding non-manufacturing Defendants and is overly broad and unduly burdensome, especially at this stage of the

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case. Wholesalers request the Court limit Plaintiffs' request to VCDs manufactured and recalled by Defendants in this litigation.

7. **DFS duplication of RFPs:** In their Plaintiff Fact Sheet ("PFS") responses, the vast majority of Plaintiffs provide only an NDC number as the definition of that Plaintiff's "Affected Drug" in the PFS. With the Defendant Fact Sheet ("DFS") draft proposed by Plaintiffs, Wholesalers would be required to produce eight years of information about that NDC (including each date, price, seller, and purchaser for every purchase/sale of that NDC number). Thus, Plaintiffs' proposed PFS/DFS process becomes sheer duplication of the RFPs and not at all tailored to information relevant to an individual Plaintiff/PFS, in violation of this Court's stated intent that DFSs are not to duplicate discovery sought through the RFP process. To remedy this issue, Wholesalers request that the Court order that the PFS pertain to a defined "Plaintiff Usage Period" that: 1) identifies the dates each Plaintiff was taking a specific generic VCD by NDC code; and 2) does not include dates during which each Plaintiff used branded VCDs.
8. **Discovery about discovery:** Several categories of information sought by Plaintiffs – such as Document Retention Policies and Indemnification Provisions – are akin to "discovery on discovery" and are, therefore, generally inappropriate at this time. Collateral inquiries into how documents are kept and what contractual provisions in eight years-worth of contracts might be implicated to potentially affect later rights of co-defendants against each other are not relevant to the initial determination on which the Court directed the parties to focus: whether there is liability at all. Moreover, these efforts are clearly outside the especially narrow scope of discovery applicable to Wholesalers, given the absence of any factual allegations of wrongdoing against them. These categories of documents are not MII for Wholesalers, and Wholesalers request this Court order that Wholesalers need not produce discovery about discovery at least at this time given the state of the pleadings and the Court's focus.
9. **Jurisdictional and substantive issues:** Wholesalers have been sued in a significant MDL proceeding without allegations of wrongdoing against them and in disregard of the statutory protections provided them by legislatures across the country. Plaintiffs seek to use the position of Wholesalers as named Defendants to procure burdensome discovery that fails to advance Plaintiffs' cases and would invade the confidential and proprietary nature of Wholesalers' business for the last eight years. To date, Wholesalers have been denied the opportunity to raise challenges to personal jurisdiction, Article III standing, and/or to ferret out Plaintiffs' baseless claims through 12(b) motions. Wholesalers request this Court to permit and hear motions in order to resolve these critical issues prior to ordering burdensome and expansive discovery from Wholesalers.
10. **Mitigation of burden:** In the absence of alleged facts supporting claims of Wholesaler wrongdoing, the Wholesalers essentially stand in the case as third party discovery

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targets requested to turn over eight years of expansive and sensitive Company data when there are no cognizable claims against them. Further, the requested discovery does not help Plaintiffs advance their case even against the other Defendants. If Wholesalers are sued in this litigation primarily to provide discovery against others, they would prefer a dismissal—without prejudice if necessary—and participation by third party subpoena, so that they may avoid the significant cost associated with the heavy MDL activity. If they are here merely as “deep pockets,” the Court should handle this novel “scorched earth” approach to Defendant-naming by appropriate motion practice. The Wholesalers request that the Court impose on Plaintiffs the requirement to broadly mitigate the burdens of discovery on Wholesalers for the reasons stated above, and as to specific discovery ordered, enter an appropriate cost-shifting order per Federal Rules of Civil Procedure 45.

2. Improvidently Filed Short Form Complaints

On January 14, 2020, Defendants filed a list of Plaintiffs who had not properly filed and served a Short Form Complaint (“SFC”) through MDL Centrality as required by this Court’s orders. *See* Dkt. 338-4, Exhibit D (providing list of delinquent Plaintiffs). Since then, the parties have been communicating to identify and resolve deficiencies in the SFCs.

A small number of Plaintiffs have failed to correct their deficiencies after being listed in several of Defendants’ filings and being ordered by the Court to correct their deficiencies. *See* Order dated Jan. 16, 2020, Dkt. 342. These Plaintiffs are identified in Exhibit A, Table A (listing Plaintiffs who have appeared on Improvidently Filed SFC list more than once). Defendants respectfully request that the Court dismiss these actions as improperly filed.

In addition, Exhibit A, Table B identifies recent SFCs that were improperly or incorrectly filed and served. Defendants hope that the parties can resolve these deficiencies by the Case Management Conference at the end of next month. For any SFC in Table B that remains deficiently filed or served by the March CMC, Defendants intend to seek dismissal at that time.

3. Over-identification of Defendants in Short Form Complaints

As raised in Defendants’ letter in advance of the February 13 conference, some Plaintiffs are filing SFCs identifying each and every Defendant at various levels of the supply chain. *See* Dkt. 368 at 3-4. Specifically, many Plaintiffs have filed SFCs that identify each and every Defendant above the retailer/pharmacy level. This overidentification is problematic and inappropriate, and implicates Rule 11. *See* 7/10/19 Tr. at 22:16–18; 2/13/20 Tr. at 11:14–19; and 1/28/20 Tr. at 55:25–56:5

Accordingly, the Court has ordered the Plaintiffs identified in Dkt. 368 Exhibit C to file Amended SFCs by March 13. *See* Feb. 19, 2020 Order, Dkt. 377 at ¶ 5. In Exhibit B attached to the present filing, Table A contains an updated version of the list of Plaintiffs ordered to meet the March 13 deadline, with the Plaintiffs’ law firms added. In addition, Table B in Exhibit B identifies

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recently filed SFCs that overidentify Defendants in violation of Rule 11. Defendants request that the Court order the Plaintiffs in cases listed on Exhibit B, Table B to amend their SFCs in accordance with Federal Rule of Civil Procedure 11 by March 20, and that to the extent such amendment does not take place by that deadline, Defendants may be permitted to seek sanctions.

4. Plaintiff Fact Sheets – Show Cause Listing

Pursuant to Case Management Order No. 16 (Dkt. 249), Defendants provide a list of those cases in which Plaintiffs have not filed a substantially complete Plaintiff Fact Sheet. In each of these cases, Defendants have served a deficiency notice, and two weeks or more have elapsed since the deficiency notice, with no adequate remedying of the Fact Sheet. This list is attached as Exhibit C.

5. Search Terms & ESI Update

The Manufacturer Defendants have begun to raise search term issues with Plaintiffs' counsel and will continue to do so as issues arise. At this time, the Manufacturer Defendants expect to be able to resolve these issues without the assistance of the Court and will promptly raise impasses if any arise. Because this is an iterative process involving refinement after refinement, the Manufacturer Defendants expect that certain terms may take a while to work out. For example, it may not be evident that certain terms are problematic until document reviewers point out frequent mis-hits. This process is expected to reduce the ultimate length of the document review, and it will take place concurrently with the document review related to documents containing search terms that are not problematic.

Following an initial meet and confer, the Mylan Defendants are developing a detailed counter-proposal regarding ESI custodian search terms. The objective is to create a revised set of search terms that are tailored to Mylan-specific issues and documents. This is necessary due to the overbreadth of the documents captured by Plaintiffs' proposed search terms, which would result in significant costs to Mylan to process, store, and review millions of irrelevant and unresponsive documents. Mylan intends to continue the meet and confer process with the Plaintiffs regarding this issue.

6. Losartan and Irbesartan Update

Plaintiffs have represented that they will need to review and possibly modify their leadership composition and draft master pleadings to address their losartan and irbseartan-related claims. *See, e.g.*, 01/29/20 Tr. at 14-15. Defendants look forward to Plaintiffs' update.

7. Amendment of Economic Loss Master Class Complaint

The Court has granted Plaintiffs leave to amend the Economic Loss Master Complaint by March 13, 2020. *See* Dkt. 377 ¶ 8. On February 19, Plaintiffs sent a proposed Amended Economic Loss Master Complaint to Defendants. On February 25, Defendants responded indicating that they

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opposed amendment. Defendants therefore await Plaintiffs' motion for leave to amend per Local Rule 15.1. *See* 2/13/20 Tr. at 17:24–18:7 (requiring motion under local rule).

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

cc: Adam Slater, Esq. (*via email, for distribution to Plaintiffs' Counsel*)
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